DIANE GREIF-SHEPPARD, PH.D.

K102938

SEP 2 3 2011

SECTION 3

510 (K) PREMARKET NOTIFICATION SUMMARY

Date: September 20, 2010

Owner And Submitter:

AcQPoint, Inc.
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Loa Quinta, CA 92253
Tel: (760) 775-7900; Fax: (760) 775-7911
Contact : Diane Greif-Sheppard or Morris Sheppard

Proprietary Name:

AcQPoint Thermajade Massage Table Model BL-7600.

Common or Usual Name:

Thermal Massage Table

Classification Name:

Multi-Function Physical Therapy Table (21 CFR 890.5880, Product Code JFB).

Predicate Device:

Ceragem RH-1, 510 (K) number K06276

Device Description:

The AcQPoint Thermajade Massage Table is an electrically powered, motorized multi-function physical therapy table. It is intended to provide muscle relaxation therapy by delivering heat and gentle massage. The massage function is delivered by two sets of natural jade rollers mounted on carriages in both the torso and leg sections of the device, These roller carriages travel along a guide rail track which is curved to conform to the natural curve of the spine. They are moved by a cable and pulley arrangement powered by two DC motors, one each for

the torso and the leg sections.. Heat is delivered by both halogen heat lamps located inside the jade rollers and carbon epoxy heating panels on the platform beneath them. The panels emit radiant heat and the rollers conductive heat. During use, as the rollers traverse the torso and legs, the device applies light pressure as well as heat to the user.

The motion of the rollers is selectable by the user. There are three different programs as well as a manual, user controlled, mode. Two of the programs last forty minutes and concentrate the massage action on different parts of the back, as well as stopping for 20 to 30 seconds at various acupressure points, and the third lasts fifteen minutes and travels continuously up and down the entire back.

The functions of the device, the temperature settings for both the carbon/epoxy emitters and the rollers and the program selection are controlled by a wired remote control with a LED display that indicates the selected program, the temperature settings and current temperatures along with a timer.

The motion of the rollers, the temperature settings and the displays on the remote are controlled by a microprocessor unit employing a microcontroller with 28k of built-in flash ROM as well as timers, EEPROM, a UART to interface with external devices and other elements required for the proper execution of the installed software and the function of the device. The software has been verified by both single step and breakpoint checks in the debugging process and validated by final bench testing on the completed device.

The device measures 27" (68.5 cm) wide by 78" (198 cm) long and has a table height of 20" (51 cm). It weighs 160 lbs. (72 kg) and has a working weight load limit of 300 lbs. (136 kg.). It is wired for 120 volt 60 cycle current and draws a maximum of 480W.

Intended Use:

The intended use of the AcQPoint Thermajade Massage Table is to provide the user with muscle relaxation therapy by delivering heat and gentle massage. Additionally the heat elements provide topical heating for temporary relief of minor muscle and joint pain and stiffness; temporary relief of joint pain associated with arthritis; temporary increase in local circulation in the areas affected by the device and relaxation of muscles.

Technological Characteristics and Substantial Equivalence:

The AcQPoint Thermajade Massage Table and the predicate device both provide heat by both carbon/epoxy heating elements under the roller carriages and halogen heating lamps mounted within the rollers, which heat them. The temperature is user-controlled and limited for

safety. In both The AcQPoint Thermajade Massage Table and the predicate device the massage function is delivered by jade rollers that are mounted on a carriage which travels along a curved track corresponding to the curvature of the spine and which is pulled by a cable and pulley mechanism powered by a small electric motor. A microprocessor chip pre-programmed with three different cycles, as well as a manually controlled cycle, controls the forward and back action of the motion. This is identical to the predicate device. Both devices are controlled by wired handheld remotes with LED displays. Both devices are constructed with all elements mounted on a platform that is surrounded with a dense polyurethane foam mattress that is cut out where the roller mechanism operates. Both have synthetic leather zippered covers.

The AcQPoint Thermajade Massage Table differs from the predicate device only in the particular shape of the jade rollers, that it also provides a second set of rollers powered by an additional motor to massage the leg area, that it has an additional roller attached to the carriage in the torso area to provide massage to the neck area and has a torso section that can be tilted up to an approximate 30 degree angle by means of a small motor should the user so desire.

These distinctions do not negatively impact the safety or effectiveness of the device.

Performance Data:

Testing was performed to ensure that the device operates in a therapeutic heat range while maintaining safety. These tests show that the tables, after the warm-up period, consistently deliver skin temperatures of between 40° C and 42.5° C for the entire period of use. This is within the range considered therapeutic and below that considered to pose a risk of burn.

There are no performance standards for this type device but, as with the predicate device, the AcQPoint Thermajade Massage Table bears the CE mark. An independent testing laboratory has confirmed conformance to the following standards:

ISO/IEC 60601-1: Medical Electrical Equipment—Part 1: General Requirements for Safety.

ISO/IEC 60601-1-2: collateral standard: Electromagnetic compatibility for medical devices.

Risk analysis:

We have conducted a risk analysis with consideration of ISO 14971:2007, application of risk management to medical devices, and relevant FDA guidance documents. We have found no unmitigated risks

that pose any unacceptable hazard and that it is a device with a minor level of concern.

Conclusion:

The AcQPoint Thermajade Massage Table Model BL-7600 has the same intended use, with similar functional and performance characteristics and has met similar standards as the predicate device. They are substantially equivalent. Other distinctions do not negatively impact the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AcQpoint Inc.
% Mr. Morris Sheppard
79-825 Highway 111, Suite 101
Loa Quinta, California 92253

SEP 23 2011

Re: K102938
Trade/Device Name: AcQPoint Thermajade Massage Table
Regulation Number: 21 CFR 890.5880
Regulation Name: Multi-function physical therapy table
Regulatory Class: II
Product Code: JFB
Dated: September 13, 2011
Received: September 13, 2011

Dear Mr. Sheppard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 102938

Device Name: AcQPoint Thermajade Massage Table

Indications For Use:

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* temporary relief of minor muscle and joint pain and stiffness;
* temporary relief of joint pain associated with arthritis
* temporary increase in local circulation in the areas affected by the device
* relaxation of muscles.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102938

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